REMARKS

This is in response to the Restriction Requirement (Paper No. 0506) mailed 9 May 2006.

Claims 1 through 18 are pending in this application.

Claims 6, 13, 16 and 18 have been amended by this Amendment to correct typographical errors.

No new matter has been added.

I. Restrictions Requirement

In the Restriction Requirement (Paper No. 0506) dated 9 May 2006, the Examiner required Applicant to elect among the inventions of Groups I through VI:

I. Claims 1-7, drawn to a method for controlling inventions is required under 35 U.S.C. 121: individual, classified, e.g., in class 424, subclass 93.7;

II. Claims 8-9, drawn to a method for controlling elevated blood glucose level in an individual, classified, e.g., in class 514, subclass 18;

III. Claims 10-13, drawn to a method for preventing chronic inflammation due to the presence of or potential exposure to a pathogen, environmental particulates or environmental toxins, classified, e.g., in class 514, subclass 19;

IV. Claims 14-16, drawn to a method for mitigating a symptom in a patient, said symptom characteristic of an inflammation-related metabolic disturbance, classified, e.g., in class 514, subclass 19;

V. Claim 17, drawn to a method for deferring the progression of a patient from the Metabolic Syndrome, classified, e.g., in class 514, subclass 18; and

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VI. Claim 18, drawn to a method for preventing or mitigating development of inflammation-related sequelae of exposure of a person to liquids or vapors containing organic solvents or hydrocarbon fuels, classified, e.g., in class 514, subclass 19.

In response to the Restriction Requirement (Paper No. 0506) dated 9 May 2006, Applicant provisionally elects Group I on which claims 1 through 7 are readable with traverse.

The Examiner failed to present a *prima facie* showing supporting the restriction requirement.

First, the examiner's classification is not proper.

To make a restriction requirement, "a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in the MPEP §802.02" (MPEP §803).

Group I was classified in Class 424, subclass 93.7. According to United States Classification System, Class 424 is defined as "DRUG, BIO-AFFECTING AND BODY TREATING COMPOSITIONS", and Subclass 93.7 is defined as "This subclass is indented under subclass 93.1. Subject matter involving animal cells, per se, such as specific cells from tissue or blood, or plant cells, per se."

Groups II and V were classified in class 514, subclass 18. According to United States Classification System, Class 514 is defined as "DRUG, BIO-AFFECTING AND BODY TREATING COMPOSITIONS[:] Class 514 is an integral part of Class 424. It incorporates all the definitions and rules as to subject matter of Class 424," and Subclass 18 is defined as "This

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subclass is indented under subclass 2. Subject matter which contains an uninterrupted peptide chain of 3 or 4 peptide units."

Groups III, IV and VI were classified in class 514, subclass 19. According to United States Classification System, Class 514 is defined as "DRUG, BIO-AFFECTING AND BODY TREATING COMPOSITIONS[:] Class 514 is an integral part of Class 424. It incorporates all the definitions and rules as to subject matter of Class 424," and Subclass 19 is defined as "This subclass is indented under subclass 2. Subject matter which contains an uninterrupted peptide chain of 2 peptide units."

The examiner's classification is clearly wrong. All the independent claims are directed to the methods including the administration of the pharmaceutical composition selected from the group consisting of YG-Product, YGG-Product, Purified Leukocyte Dialysate Subfraction, and a combination thereof. There is no reason to classify the claims into different classes. If the examiner wants to classify Group I invention in class 424, 93.7, all the other Group inventions should be classified in the same class in view of the above definitions of the classes and subclasses. Furthermore, it is hardly understood why Groups II and V were classified in class 514, subclass 18 which is directed only to an uninterrupted peptide chain of 3 or 4 peptide units, whereas Groups III, IV and VI were classified in class 514, subclass 19 which is directed only to an uninterrupted peptide chain of 2 peptide units. As stated above, all the groups recite the administration of the pharmaceutical composition selected from the group consisting of YG-Product, YGG-Product, Purified Leukocyte Dialysate Subfraction, and a combination thereof. Moreover, the definition of class 514 clearly states that "Class 514 is an integral part of Class 424. It incorporates all the definitions and rules as to subject matter of Class 424." In addition,

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Groups II and V were classified in the same class, and Groups III, IV and VI were classified in the same class.

The examiner did not properly show separate classification, separate status in the art, or a different field of search as defined in the MPEP §802.02.

Since the examiner failed to present a *prima facie* showing supporting the restriction requirement, the restriction requirement should be withdrawn.

Furthermore, even if the claims of Invention groups I through VI may respectively have separate utility from each other, there is overlapping subject matter recited in the groups, negating a serious burden on the examiner for searching the groups. For example, as stated above, all the claims recite the administration of the pharmaceutical composition selected from the group consisting of YG-Product, YGG-Product, Purified Leukocyte Dialysate Subfraction, and a combination thereof.

As stipulated in *MPEP* §803, since there is no serious burden, the Examiner must examine the entire application on the merits. Furthermore, respectfully, as shown above, a *prima facie* case of a restriction requirement has not been proven by the examiner.

II. Requirement of Election of Species

The Examiner further required Applicant to elect species among compositions to be used and species among chronic inflammation conditions to be treated, and species among Metabolic Syndrome diseases to be treated.

The Applicant provisionally elects YG Product as a composition to be used, and obesity associated with the Metabolic Syndrome as a chronic inflammation condition to be treated, and

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obesity as a Metabolic Syndrome disease to be treated, with traverse. As admitted by the examiner, all the claims are generic. Accordingly, all the claims are readable thereon.

The examiner's requirement is not proper for the following reasons.

First, since there is no serious burden, the Examiner must examine the entire application on the merits.

MPEP §803.02 states that:

"If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.

Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984)."

Here, the members of the Markush group (*i.e.*, alleged species) are sufficiently few in number or so closely related to a search and examination of the entire claim.

Also, the subject matter in a claim has unity of invention. The compositions to be used (e.g., YG-Product, YGG-Product, Purified Leukocyte Dialysate Subfraction or combination

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thereof) are the "selected immunoregulators"[1] which is defined in the prior art and the specification, and share a common utility and share a substantial structural feature disclosed as being essential to that utility.

With respect to the recited chronic inflammation conditions and the recited Metabolic Syndrome diseases, all the alleged species are components of the Metabolic Syndrome (ICD Code 277.7, also known as Dysmetabolic Syndrome). In this regard, the subject matter in a claim has unity of invention.

Since the members of the Markush group are sufficiently few in number and so closely related that a search and examination of the entire claim can be made without serious burden, and the subject matter in a claim has unity of invention, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions.

Withdrawal of the restriction requirement is respectfully requested.

No fees are incurred by this Amendment.

[1] "The "selected immunoregulators" ("selected immunormodulators" "selected immunoamplifiers") include the purified Leukocyte Dialysate Subfraction (LDS) described by Dr. A. Arthur Gottlieb Patents (U.S. Pat. Nos. 5,100,663, 4,616,079, 4,699,898, 4,710,380, 4,778,750, 4,874,608, 5,013,546, 5,081,108, 5,093,321 which are incorporated herein by references) which is naturally derived from healthy human leukocytes, as well as purified immunologically active components of the naturally derived immunoregulators including the dipeptide tyrosylglycine (YG) and the tripeptide tyrosylglycylglycine (YGG), as well as synthetically produced YG and YGG. These regulators also include covalently modified YG and YGG, such modifications designed to stabilize or to enhance the biological activity of said regulators, as well as pharmaceutically acceptable salts, suitable for human use, of YG, YGG, and related molecules including covalently modified YG, and covalently modified YGG." (See paragraph [0041] in the specification.)

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In view of the foregoing election, this response is believed to be a complete response to the Requirement for Restriction. Should any questions remain unresolved, the Examiner is requested to contact the Applicant.

Respectfully submitted,

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